MAY - 9 2003

K031008



# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**COMPANY:** Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

**CONTACT:** Matthew M. Hull, Sr. Regulatory Affairs Associate
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**TRADE NAME:** Aesculap Neuro Patties

**COMMON NAME:** Cottonoid Paddie

**DEVICE CLASS:** CLASS II

**PRODUCT CODE:** 84 HBA

**REGULATION:** 882.4700

**REVIEW PANEL:** Neurology

## INTENDED USE

Aesculap's Neuro Patties are intended for use during surgery to protect nervous tissue, absorb fluids, or stop bleeding during neurological and other general procedures.

## DEVICE DESCRIPTION

Aesculap's Neuro Patties are rectangular fluid absorption pads for use during neurological and/or general procedures. The devices are available in a variety of dimensions, with widths from 4mm to 70mm and lengths from 6mm to 150mm. The material used for the patties is natural woven cotton fiber, this material is available in either a tight weave (neurosorb 4 or 6) or a more open gauze-like weave (neurosorb 75). The neurosorb 4 material consists of 4 layers while neurosorb 6 is constructed with 6 layers, the layers provide different levels of absorbency for surgeon preference. All patties have a suture string attached for ease in count verification, they are also available with x-ray detectable markers if desired. The patties are packaged 10 per card in either single size sets or in procedure (indication) sets with a variety of sizes. These devices are for single use only and should not be resterilized.

## PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Aesculap Neuro Patties.

## PERFORMANCE STANDARDS

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

## SUBSTANTIAL EQUIVALENCE

The Aesculap Neuro Patties described in this premarket notification are substantially equivalent to these predicate devices:

- Codman Surgical Pattie (K880402)
- Pacific Surgical Patties (K993019)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Aesculap, Inc.
c/o Mr. Stefan Preiss
TÜV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K031008
Trade/Device Name: Neuro Patties
Regulation Number: 21 CFR 882.4700
Regulation Name: Cottonoid Patties
Regulatory Class: II
Product Code: HBA
Dated: April 22, 2003
Received: April 24, 2003

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

**510(k) Number** (if known): K031008

**Device Name:** Neuro Patties

**Indication for Use:**

Aesculap's **Neuro Patties** are intended for use during surgery to protect nervous tissue, absorb fluids, or stop bleeding during neurological and other general procedures.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031008

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)